IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEMS PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL 2327
ETHICON WAVE 8 CASES LISTED IN EXHIBIT A OF DEFENSE NOTICE OF ADOPTION	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

PLAINTIFFS' RESPONSE IN OPPOSITION TO DEFENDANT ETHICON INC.'S MOTION TO EXCLUDE OR LIMIT CERTAIN GENERAL OPINIONS AND TESTIMONY OF KONSTANTIN WALMSLEY, M.D.

COMES NOW Plaintiffs in the above styled cause ("Plaintiffs"), and hereby adopt and incorporate by reference the responses to Daubert motions filed against Konstanin Walmsley in Waves 1 (dkt 2171), 3 (dkt 2941, 2953) and 4 (dkt 3783) and submit the following combined response and memorandum of law in Opposition to Defendant Ethicon, Inc.'s ("Ethicon") Motion to Exclude Certain General Opinions and Testimony of Dr. Konstantin Walmsley, state as follows:

INTRODUCTION

Dr. Walmsley is a board-certified urologist. Dr. Walmsley is trained through education and experience with the evaluation and treatment of stress urinary incontinence. He has implanted synthetic transvaginal mesh and is familiar with the properties and implantation technique of the same. *See* Expert Reports of Dr. Walmsley, Defendants' Exhibits A, B, and C, Doc. No. 6879-2, 6879-3, 6879-4, at p. 1. Dr. Walmsley attended and is familiar with training provided by the Defendant manufacturer with regard to all Ethicon's products. *See id.* He has performed explant and revision procedures on a variety of retropubic and transobturator midurethral slings. *Id.* Through his education, training, and experience, Dr. Walmsley is familiar

with the complications associated with mesh repair surgery and is experienced in the recognition, diagnosis, and treatment of patients suffering from complications caused by pelvic mesh repair. *Id.* at 2.

Ethicon does not challenge the credentials and expertise of Dr. Walmsley in matters regarding pelvic surgery and urology, but, in effect, seeks to exclude all of Dr. Walmsley's opinions that fall within the general categories detailed below. Although Ethicon correctly cites the legal standard for its Motion, it misapplies the standard and offers no basis to refute Dr. Walmsley's general opinions. Of significance, Ethicon never deposed Dr. Walmsley regarding his general opinions and case-specific opinions, which incorporated his general opinions.

LEGAL STANDARD

This Court, on many occasions has undertaken detailed instruction of the legal standards governing the admission of expert testimony. The Court has often stated that:

> Under Federal Rule of Evidence 702, expert testimony is admissible if the expert is 'qualified . . . by knowledge, skill, experience, training, or education,' and if his testimony is (1) helpful to the trier of fact in understanding the evidence or determining a fact in issue; (2) 'based upon sufficient facts or data'; and (3) 'the product of reliable principles and methods' that (4) have been reliably applied 'to the facts of the case.' Fed. R. Evid. 702. The U.S. Supreme Court established a two-part test to govern the admissibility of expert testimony under Rule 702—the evidence is admitted if it 'rests on a reliable foundation and is relevant.' *Daubert*, 509 U.S. at 597. The proponent of expert testimony does not have the burden to 'prove' anything to the court. *Md. Cas. Co. v. Therm-O-Disk, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998). He or she must, however, 'come forward with evidence from which the court can determine that the proffered testimony is properly admissible.' *Id.*

Sanchez, et al. v. Boston Scientific Corporation, 2:12-cv-05762, Doc. 148, at *3 (S.D.W.Va. Sept. 29, 2014). Furthermore:

> The district court is the gatekeeper. It is an important role: '[E]xpert witnesses have the potential to be both powerful and quite misleading[;]' the court must 'ensure that any and all scientific testimony . . . is not only relevant, but reliable.' *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (citing *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999) and *Daubert*, 509 U.S. at 588, 595). In carrying out this

> role, I 'need not determine that the proffered expert testimony is irrefutable or certainly correct'—'[a]s with all other admissible evidence, expert testimony is subject to testing by 'vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.' *United States v. Moreland*, 437 F.3d 424, 431 (4th Cir. 2006) (quoting *Daubert*, 509 U.S. at 596); *see also Md. Cas. Co.*, 137 F.3d at 783 (noting that "[a]ll *Daubert* demands is that the trial judge make a 'preliminary assessment' of whether the proffered testimony is both reliable . . . and helpful").

Id. at *3-4 (footnote omitted).

> *Daubert* mentions specific factors to guide the court in making the overall reliability determinations that apply to expert evidence. These factors include (1) whether the particular scientific theory 'can be (and has been) tested'; (2) whether the theory 'has been subjected to peer review and publication'; (3) the 'known or potential rate of error'; (4) the 'existence and maintenance of standards controlling the technique's operation'; and (5) whether the technique has achieved 'general acceptance' in the relevant scientific or expert community. *United States v. Crisp*, 324 F.3d 261, 266 (4th Cir. 2003) (quoting *Daubert*, 509 U.S. at 593–94).
>
> Despite these factors, '[t]he inquiry to be undertaken by the district court is 'a flexible one' focusing on the 'principles and methodology' employed by the expert, not on the conclusions reached.' *Westberry*, 178 F.3d at 261 (quoting *Daubert*, 509 U.S. at 594–95); *see also Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999) ("We agree with the Solicitor General that '[t]he factors identified in *Daubert* may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony.'") (citation omitted); *see also Crisp*, 324 F.3d at 266 (noting "that testing of reliability should be flexible and that *Daubert*'s five factors neither necessarily nor exclusively apply to every expert").
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> With respect to relevancy, *Daubert* further explains:
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> Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful. The consideration has been aptly described by Judge Becker as one of fit. Fit is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes. . . . Rule 702's helpfulness standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility. *Daubert*, 509 U.S. at 591–92 (internal citations and quotation marks omitted).

Id. at *3-5.

ARGUMENT

Dr. Walmsley has offered opinions that (1) mesh products are not suitable for their intended application as a permanent prosthetic implant for the treatment of pelvic organ prolapse

and stress urinary incontinence because of the following characteristics: (a) degradation of the mesh; (b) chronic inflammation and chronic foreign body reaction; (c) mesh that was never intended to be implanted inside the pelvic cavity and is incompatible with the naturally occurring conditions of the vagina including peroxides and bacteria; (d) deformation, rigidity, fraying, roping, cording, and curling of the mesh; (e) loss of pore size with tension; (f) fibrotic bridging leading to scar plate formation and mesh encapsulation; (g) shrinkage/contraction of the encapsulated mesh; and (h) the difficulty and/or impossibility of removing the devices; (2) these mesh devices are not suitable for their intended applications as permanent prosthetic implants for pelvic floor repair in women; (3) Ethicon's construction mesh, used in [its] devices, [are] not suitable for its intended application as permanent prosthetic implants for stress urinary incontinence because the pores are too small, it is heavy weight mesh, it degrades over time, causes chronic foreign body reactions, fibrotic bridging, mesh contracture/shrinkage, fraying, particle loss, biofilm formation and infections, has sharp edges, ropes, curls, and deforms, and the pores collapse with tension; (4) Ethicon knew that its TVT-Obturator and Prolift mesh devices were not appropriate for use, but it failed to modify/change the mesh to a larger pore size, lighter weight mesh that would not degrade, cause excessive foreign body reactions or chronic inflammation, or deform, become rigid, fray, rope, or cord after implantation, and cause the formation of fibrotic bridging that leads to scar plate formation and mesh encapsulation – and that these devices are difficult or impossible to remove. According to Ethicon's internal documents, it was unwilling to change the mesh because of its economic interest in maintaining its competitive advantage in the market and, therefore, Ethicon put profits before patient safety; (5) Ethicon's … devices have design flaws because they cannot adequately describe, inform, or explain to physicians how to properly "tension" the device. Further, the devices shrink, contract,

rope, and curl making it difficult or impossible to tension in a safe manner for patients; (6) Ethicon's meshes are not suitable for permanent implant because the Material Safety Data Sheet ("MSDS") for the polypropylene resin used to manufacture Ethicon's polypropylene states that its polypropylene is incompatible with strong oxidizers such as peroxides which are readily found in the vagina; (7) Ethicon's mesh devices are also not suitable for permanent implant because the toxicity testing of the polypropylene mesh revealed that it was cytotoxic which can cause cell death and complications; (8) Ethicon's warnings and disclosures of adverse events in their Instructions for Use ("IFU") for these devices have been inadequate based on the adverse reactions and risks associated with them that have been known to Ethicon from the time these devices were first sold and marketed. Ethicon did not disclose information to physicians in their IFU regarding characteristics of their devices that makes them unsuitable for their intended application as a permanent prosthetic implant for pelvic floor repair, this includes; small pore size; heavy weight mesh; the mesh's tendency to degrade over time, cause chronic foreign body reactions, fibrotic bridging, contract, shrink, fray, lose particles, rope, curl, or deform; the pores collapse with tension; the mesh becomes difficult or impossible to remove; the mesh tested positive for cytotoxicity; and, the MSDS states that it is incompatible with strong oxidizers, such as peroxides; (9) The design of these devices are flawed because they are not designed for special patient populations, nor does the IFU nor marketing documents inform physicians that certain patients will have poorer outcomes and higher risks; (10) Ethicon failed to reveal material facts about complication and conflicts of interest regarding key studies in key marketing documents; and (11) The benefits of these mesh products are outweighed by the severe, debilitating, and life changing complications associated with them and there were safer

alternative options available. *See* Expert Reports of Dr. Walmsley, Defendants' Exhibits A, B, and C, Doc. No. 6879-2, 6879-3, 6879-4, pp. 3, 7-8.

These opinions should not be excluded under *Daubert* as they present neither improper state of mind testimony nor do they lack a reliable basis in scientific foundation. In other words, Dr. Walmsley's opinions are both reliable and relevant.

Furthermore, Defendant waived its challenges to these opinions because it did not seek, nor conduct Dr. Walmsley's deposition. Plaintiffs argue Defendants' Motion is not a proper *Daubert* challenge. For the reasons set forth below, Dr. Walmsley's opinions are admissible and Defendant's Motion should be denied.

I. Plaintiffs will agree that Dr. Walmsley's opinions regarding Ethicon's knowledge, state of mind, corporate conduct, and motives behind Ethicon documents should be excluded.

Plaintiffs state that certain opinions this Court has already addressed in previous cases and excluded will not be offered.[1] Ethicon argues that Dr. Walmsley seeks to offer testimony as to its state of mind, knowledge, and intent during product development. As this Court explained, "expert testimony about a defendant company's state of mind is impermissible." *Sanchez v. Boston Scientific Corp.*, 2:12-cv-05762, Doc. 148, at *32 (S.D.W.Va. Sept. 29, 2014). "In *Lewis*, I excluded state of mind testimony of Dr. Margolis because 'he is not qualified…to opine on Ethicon's state of mind or knowledge.'" *Id.* (citing *Lewis*, 2014 WL 186872, at *15).

However, Dr. Walmsley should not be precluded from relying upon the documentary evidence and the testimony of Ethicon executives as to what information was available to

[1] *See e.g. In re Ethicon, Inc., Pelvic Repair Systems Product Liability Litigation*, 2017 WL 1175399 (March 29, 2017); *see also In re Ethicon, Inc., Pelvic Repair Systems Product Liability Litigation*, 2016 WL 4961675 (August 25, 2016).

Ethicon at a given time, when testifying whether that information would have impacted a doctor's risk-benefit analysis if it the information was known.

II. Dr. Walmsley's general opinions regarding Ethicon's products should not be excluded.

"Under Federal Rule of Evidence 704, '[a]n opinion is not objectionable just because it embraces an ultimate issue.'" *In re C.R. Bard, Inc.*, 948 F.Supp.2d 589, 629 (S.D.W.Va. June 4, 2013) (citation omitted). "The Fourth Circuit has explained that the 'role of the district court ... is to distinguish opinion testimony that embraces an ultimate issue of fact from opinion testimony that states a legal conclusion.'" *Id.* (citation omitted). "The best way to determine whether opinion testimony contains legal conclusions, 'is to determine whether the terms used by the witness have a separate, distinct and specialized meaning in the law different from that present in the vernacular.'" *Id.* (citations omitted). Dr. Walmsley may offer his opinions "using terms that do not have a separate, distinct, and specialized meaning in the law. *See, id.*

Furthermore, in accordance with this Court's ruling in *Tyree*, Dr. Walmsley may offer opinions that the Ethicon's products are not suitable to serve as permanent implants, complications are caused by Ethicon's products, complications are caused by the defects in Ethicon's pelvic mesh products, Ethicon's pelvic mesh products Instructions for Use ("IFU") are inadequate, and there are safer, feasible alternatives to Ethicon's pelvic mesh products.

III. Dr. Walmsley's opinions regarding defective design and the properties of the Bard products are admissible.

A. Dr. Walmsley's opinions regarding design, biomaterials, and chemical properties of Ethicon's products are reliable.

For the reasons shown below, Dr. Walmsley's opinions regarding design, biomaterials, and the chemical properties of Ethicon products is reliable. "*Daubert* mentions specific factors

to guide the court in making the overall reliability determinations that apply to expert evidence." *Eghnayem v. Boston Scientific Corp.*, 57 F.Supp.3d 658, 669 (S.D.W.Va. Oct. 27, 2014).

> These factors include (1) whether the particular scientific theory 'can be (and has been) tested'; (2) whether the theory 'has been subjected to peer review and publication'; (3) the 'known or potential rate of error'; (4) the 'existence and maintenance of standards controlling the technique's operation; and (5) whether the technique has achieved 'general acceptance' in the relevant scientific or expert community.

Id. (citation omitted). "Despite these factors, '[t]he inquiry to be undertaken by the district court is 'a flexible one' focusing on the 'principles and methodology' employed by the expert, not on the conclusions reached.'" *Id.* (citation omitted).

1. Pore size and density

Dr. Walmsley's opinions related to pore size are properly applied to the facts of Plaintiffs' cases. Ethicon argues that Dr. Walmsley did not support these opinions in his report. Dr. Walmsley attached to his reports a list of medical literature that supports this opinion. Yet, Defendant did not depose Dr. Walmsley. "The relevant inquiry is whether the proffered opinions are sufficiently reliable under *Daubert*." *In re Ethicon, Inc., Pelvic Repair System Products Liability Litigation*, 2014 WL 186872, *4 (S.D.W.Va. Jan. 15, 2014). Ethicon is free to question Dr. Walmsley about this opinion on cross-examination. Dr. Walmsley's pore size and density opinions are supported by a reliable methodology. Therefore, Dr. Walmsley's opinions as to these concepts should not be excluded.

2. Cytotoxicity and MSDS caution against using Marlex polypropylene

This Court has previously "determined that the MSDS is relevant." *See, Tyree*, 54 F.Supp.3d at 577. Ethicon is attempting to seek the benefit of failing to question Dr. Walmsley about the basis of the opinions he offered in this Wave. Dr. Walmsley was not questioned or

deposed as to what published literature Dr. Walmsley relied on in support of his opinion that polypropylene is not fit for human implantation.

Ethicon has offered absolutely no studies that refute Dr. Walmsley's opinion, yet Ethicon's experts want to offer the opinions that polypropylene mesh is safe for human implantation. Dr. Walmsley's opinion regarding Marlex polypropylene is based on the MSDS. Although Dr. Walmsley's opinion is grounded on the MSDS, his testimony is admissible due to the potential need for rebuttal testimony based on what Bard presents at trial. *See, Mathison v. Boston Scientific Corp.*, 2015 WL 2124991, *32 (S.D.W.Va. May 6, 2015). Therefore, Ethicon's Motion should be denied.

IV. Dr. Walmsley's product labeling and warning opinions should not be excluded

Dr. Walmsley has offered the opinion that Plaintiffs' physicians were not aware of the extent or severity of the risks involved in the implantation of the Ethicon slings. Defendant has attempted to exclude this testimony by simplifying and mislabeling the opinions as unsupported and improper. The opinions themselves are not improper state of mind testimony. Rather, Dr. Walmsley is opining here, as he has in prior Waves, to information relayed to the medical community by the Defendant and information concealed from the medical community by the Defendant. Dr. Walmsley is opining that Plaintiffs' implanting physicians were unaware of the extent of the risks *because* the Defendant ensured that the medical community was unaware of the risks. Defendant overlooks the core issue in a medical device products liability litigation. Liability for a defective product does not turn on the subjective information contained within a surgeon's mind, rather on risks known to manufacturers and not communicated to the medical community; moreover, known risks that were deliberately concealed.

As with any *Daubert* motion, it is critical to examine the facts upon which the expert's testimony relies. Here, Dr. Walmsley bases his opinions on: the warnings contained in the Instructions for Use ("IFU"), the General Liability Reports of Drs. Rosenzweig, Shobeiri, and Ostergard (collectively, "General Liability Reports"), Defendant's corporate documents, and his own experience, education, and training. *See*, Ethicon's Exhibit B, C, and D at pp. 11, 12-15. The pertinent facts contained, and missing, from each of these sources permitted Dr. Walmsley to form the opinion that the Defendant withheld information from the medical community regarding the risks of the Defendant's devices and minimized risks in the IFUs.

1. Dr. Walmsley's opinions regarding the inadequacy of the IFUs and Ethicon's failure to adequately warn implanting physicians are reliable.

As indicated above, Dr. Walmsley opined that patients implanted with the Ethicon slings were prevented from giving true informed consent as a result of Ethicon's inadequate labeling. If he was deposed, Dr. Walmsley would have offered a list of warnings and risks that he believed should have been included in the IFUs. Dr. Walmsley's opinions about labeling are relevant to Plaintiffs' failure to warn claims. "To assess the validity of this claim, the jury will need to understand what information should be included in IFUs and patient brochures but was not included by [Ethicon]—the plaintiffs argue that Dr. [Walmsley] can provide such understanding to the jury." *See*, *Eghnayem*, 57 F.Supp.3d at 696. In *Eghnayem*, this Court "agree[d] that such testimony might help guide the jury in reaching a verdict on these state law claims, which consider the appropriateness of product labeling, and as such, [the] opinions are relevant." *Id.*

To the extent that Ethicon seeks to exclude all of Dr. Walmsley's opinions and testimony regarding the inadequacy of the IFUs and Bard's failure to adequately warn implanting physicians of the risks of Bard's products, this motion should be denied.

V. All of Dr. Walmsley's general opinions are admissible since Ethicon failed to depose him.

Defendant waived its objections to Dr. Walmsley's general opinions because it failed to depose him. Defendant, in essence, is seeking to benefit from its own neglect. As already indicated above, Dr. Walmsley offered significant support for his general opinions. Dr. Walmsley reviewed corporate documents which plainly state that Defendant representatives were aware of risks but made no effort to communicate this information to surgeons such as Plaintiffs' implanters. Further, Dr. Walmsley reviewed the depositions of Plaintiffs which circumstantially supported his opinion that Plaintiffs' implanting surgeon did not communicate certain risks to them. Moreover, Dr. Walmsley has relied upon his knowledge, training, education, and experience as a urologist. Finally, and most importantly, Dr. Walmsley relied on significant medical literature which support his opinions. Therefore, all of Dr. Walmsley's opinions are reliable and should not be excluded.

CONCLUSION

WHEREFORE, Defendant's Motion to Exclude Certain Opinions and Testimony of Dr. Walmsley should be denied as to all of his so-called general opinions as Defendant has not sufficiently challenged their admissibility and all opinions pass scrutiny under *Daubert*.

Dated: October 23, 2018

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on October 23, 2018, I electronically filed the foregoing document with the Clerk of the court using CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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